UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,604	10/28/2004	Betty M Rozier	04308057	9589

26565 7590 10/08/2009

MAYER BROWN LLP
P.O. BOX 2828
CHICAGO, IL 60690

EXAMINER	
JACKSON, BRANDON LEE	
ART UNIT	PAPER NUMBER
3772	

NOTIFICATION DATE	DELIVERY MODE
10/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,604	ROZIER ET AL.	
	Examiner	Art Unit	
	BRANDON JACKSON	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *2-30 and 40-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/2009 has been entered.

Response to Arguments

Applicant's arguments with respect to 35 U.S.C. 112, first paragraph rejection are found to be persuasive and the 112 rejection is hereby withdrawn.

Applicant's arguments with respect to the 35 U.S.C. 103(a) are not persuasive; see response to affidavit below.

Oath/Declaration

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Shesol reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir.

1897). Applicants have provided evidence that they conceived an IV house having a flange, which is supported by Exhibit A, Figures 1-6. However, that Exhibit does not disclose a fabric connector affixed to the flange that does not traverse the sidewall of the house, as disclosed in Claim 1. Applicants has provided evidence that they conceived welding the fabric connector to the edges of an IV house and the IV house if full exposed, which is shown in Exhibit B, Figure 7. However, Exhibit B discloses no flanges upon the housing. Therefore, it would not be proper for The Office to assume that Applicant's contemplated using both features together until the instant application because Applicant has not provided definitive evidence that they had conceived or reduced to practice an IV housing having a flange with a fabric connector attached to the flange, that also does not traverse the sidewall of the housing, as stated in Claim 1.

Moreover, it appears that the new features added in the instant continuation-in-part application is the IV housing having a flange with a fabric connector attached to the flange, which also does not traverse the sidewall of the housing. Therefore, this is also evidence that Applicants had not conceived the limitations of Claim 1 until a later date.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 34, and 38-39 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,526,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the limitations of Application claim 1 can be found in claim 1 of Patent '981. With respect to claim 34, all the limitation can be found in claims 1-3 of the '981. With respect to claims 38-39, all the limitations can be found in claims 1-5 of '981.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) in view of Grabenkort et al. (US Patent 4,237,010). Shesol discloses a hollow member (30) having a base (32); an edge positioned upon the patient (fig. 1); hollow member width, height, and length are sufficient to straddle and cover the site (18). The base (32) is joined with the sidewall to form a cover (12). At least one fabric connector (46) is affixed to the hollow member (30). A hook and loop (68), an adhesive (col. 5, lines 36-39), or an ultrasonic bonding (col. 5, lines 36-39) can be used as the means to affix the fabric connector (46) to the hollow member (30). Hook and loop fasteners (52) are the means used to close the fabric connector (46) on the patient (16). Shesol fails to disclose the hollow member has a flange attached to the lower edge of the hollow member. However, Grabenkort teaches a site guard (10) comprising a hollow member (12) having a flange (16) attached to the lower edge of the hollow member (12). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Shesol device to have a flange, as taught by Grabenkort, because the flange provides the device with greater surface area contacting the patient, which would in turn better stabilize the device and prevent movement of the guard while in use. Moreover, it would be obvious to one of ordinary skill in the art that the fabric connector (46) could be affixed to the flanges, as taught by Shesol/Grabenkort, because the fabric connector (46) is merely connected to the edges of the hollow member (30), not traversing the sidewall, as shown in Figure 3. The edge

of the Shesol/Grabenkort hollow member (30) is the flange (16).

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) and Grabenkort et al. (US Patent 4,237,010) in view of Hely (US Patent 6,142,966). Shesol/Grabenkort substantially discloses the claimed invention, see claim 1 rejection above. Shesol/Grabenkort fails to disclose at least one opening to accommodate a body part or the first and second opening to accommodate the right and left thumb. However, Hely teaches a wrap (10) comprising a thumbhole (25). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Shesol/Grabenkort wrap with a thumbhole, as taught by Hely, because it would prevent the device from moving up and down on the hand. Moreover, it would have been obvious to one of ordinary skill in the art at the time of the invention to add another thumbhole adjacent to the current thumbhole to accommodate a right or left thumb, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) and Grabenkort et al. (US Patent 4,237,010) in view of Bierman (US Patent 5,722,959). Shesol/Grabenkort substantially discloses the claimed invention; see rejection to claim 1 above. Shesol/Grabenkort also discloses a hook and loop means (68) for affixing the wrap (46) to the sidewall of the hollow member (30).

Shesol/Grabenkort fails to disclose cushion attached to the fabric connector opposite the lower edge of the hollow member. However, Bierman teaches a catheter securement device (10) with a cushion (18) disposes between the device (10) and the user's skin. Therefore, it would have been obvious to one of ordinary skill in the art to modify the Shesol/Grabenkort device with a cushion, as taught by Bierman, in order to provide the user more comfort while the device is secured to the skin.

Claims 36-37 rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) and Grabenkort et al. (US Patent 4,237,010) in view of Nix (US Patent 5,807,300). Shesol/Grabenkort substantially discloses the claimed invention; see rejection to claims 1 and 34 above. Shesol/Grabenkort fails to disclose tubular mesh comprising openings to accommodate various body parts. Nix teaches a wrap (16) made of tubular mesh (col. 1, lines 58-59). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to substitute the undisclosed material of Shesol/Grabenkort for the tubular mesh, as taught by Nix, in order to allow air flow and elasticity so the wrap will fit all size hands.

Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shesol (US Patent 6,257,240) and Grabenkort et al. (US Patent 4,237,010) in view of Shultz (US Patent 6,132,399). Shesol/Grabenkort substantially discloses the claimed invention; see rejection to claim 1 above. Shesol/Grabenkort fails to disclose an agent in the fabric connector and where the agent is selected to be one of antimicrobial,

antifungal, antiviral, aloe, vitamin E, and combinations of any of the foregoing. However, Shultz teaches an intravenous securement dressing (10) comprising antimicrobial compound, antifungal compound or vitamins (col. 5, lines 25-28). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Shesol/Grabenkort fabric connector with an antimicrobial or antifungal compound in order to aid in the healing in the intravenous site and to prevent infection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

/BLJ/

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772